

REMARKS

Claims 1-47 are pending, and claims 1-4, 6-14, 22-24 and 26-39 are currently under consideration. Applicants will cancel non-elected claims upon indication of allowable subject matter. Applicants add new claims 48-59. Support for the subject matter of these claims is found throughout the specification. No new matter has been entered. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1-2. Applicants note with appreciation the Examiner's modification of groups I, II and IV. Applicants further note that the amendment filed March 8, 2002 has been entered in full. Claims 1-4, 6-14, 22-24 and 26-39 are currently under consideration.

3. The declaration is objected to for allegedly being defective. Applicants submit herewith a substitute declaration which is believed to satisfy all of the requirements under 37 CFR 1.67(a).

4-5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants traverse this rejection to the extent that it is maintained in light of the amended claim.

Claim 3 is specifically rejected because claim 2 allegedly fails to provide proper antecedent basis for the limitation "EC50/IC50". Applicants' amendment to claim 3 obviates the rejection.

6. Claims 22-24 and 26-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse this rejection to the extent that it is maintained in light of the amended claims.

a. Claim 22 is rejected over the recitation of the phrase "characterized by." Applicants maintain that the term "characterized by" is routinely used in the art in reference to the traits which comprise a particular biological condition. Accordingly, the use of the term in

the context of the present application is clear, and one of skill in the art can readily appreciate the metes and bounds of the claimed subject matter. Nevertheless, to expedite prosecution, Applicants have amended claim 22 to incorporate the clarifying language suggested by the Examiner. Applicants' amendment is made solely for clarity and to expedite prosecution, and is not in acquiescence of the rejection. Furthermore, Applicants contend that the amendment does not narrow the scope of the claims. Reconsideration and withdrawal of this rejection are respectfully requested. ✓

b. Claim 39 is rejected for allegedly lacking clarity. Applicants amendment to claim 39 is believed to obviate the rejection.

7-8. Claims 3, 23 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. Applicants traverse this rejection to the extent that it is maintained in light of the amended claims.

Claims 3, 23 and 36-38 are specifically rejected because the specification allegedly fails to provide literal support for the claimed subject matter, and thus particular limitations recited in these claims allegedly constitute new matter. Applicants contend that in accordance with MPEP 2163, the standard for satisfying the written description requirement does not require *in haec verba* support for the limitations recited in the claims. To comply with 35 U.S.C. 112, first paragraph, the requirement is that claim limitations are "supported in the specification through express, implicit, or inherent disclosure." (MPEP 2163). Applicants contend that the pending claims satisfy this burden, and that the application provides implicit and/or inherent support for the limitations recited in the claims.

Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended claims 3, 23, and 36-38. Applicants' amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested. ✓

9. Claims 1-4, 6-14, 22-24 and 26-39 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to enable one of skill in the art to make or use the claimed invention. Applicants traverse this rejection to the extent that it is maintained in light of the amended claims.

The basis of the rejection appears to be two-fold. Firstly, does the specification enable one of skill in the art to practice the invention commensurate with the scope of "elastin-based compositions" and secondly does the specification enable one of skill in the art to practice the invention based on any route of administration of the elastin-based compositions.

Applicants contend that the specification is broadly enabling for pharmaceutical preparations of elastin-based compositions for administration to target sites in vivo. Nevertheless, to provide further clarity and guidance to one of skill in the art, Applicants have amended the claims to more particularly point out the claimed subject matter. The amended claims describe the elastin-based compositions in terms of both structural attributes, as well as functional attributes. As such one of skill in the art has ample information to make and use the invention. Accordingly, Applicants contend that the claims are enabled throughout their scope.

The second basis for the rejection is based on the routes of administration of the elastin-based compositions. The Examiner has alleged that the in vivo efficacy of a composition may be largely based on the route of administration, and thus the pending claims are of unduly broad scope. Although differences in efficacy of a composition based on route of administration may be relevant to the eventual FDA approval and use of a pharmaceutical composition, this issue is not relevant to the question of the patentability of the claimed subject matter. The claims are explicitly limited to compositions having particular functional attributes. As such, the claims are already limited to compositions capable of evoking a particular response upon administration. Accordingly, compositions which do not evoke that response or that fail to evoke that response when administered via a particular route already lie beyond the scope of the claimed subject matter.

Additionally, even if the Examiner is not satisfied that certain inoperative subject matter is outside the scope of the pending claims, Applicants point out that "the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled"

(MPEP 2164.08(b)). "The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art." (*Atlas Power Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409 414 (Fed Cir. 1984)).

Applicants contend that the specification is broadly enabling for a range of elastin compositions, as well as for numerous routes of administration of such elastin compositions. Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to more particularly point out aspects of the route of administration. Applicants' amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. In light of Applicants' amendments and arguments of record, reconsideration and withdrawal of this rejection are respectfully requested.

10-11. Claims 1, 10 and 12 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Ito et al. Applicants traverse this rejection to the extent that it maintained in light of the amended claims.

To anticipate Applicants' invention, the prior art must teach each and every limitation of the pending claims (MPEP 2131). This standard has been reiterated in the holdings of the Federal Circuit. "A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Accordingly, to maintain the rejection, the Examiner must conclude that Ito et al. teaches each and every element of the pending claims. Applicants contend that Ito et al. fails to satisfy this standard.

Ito et al. discloses the results of in vitro studies which demonstrate that α -elastin provided in a collagen gel can inhibit smooth muscle cell proliferation. Ito et al. fails to provide evidence that these methods and compositions can be used for influencing cell behavior in vivo, as provided by the presently claimed invention. Furthermore, Ito et al. fails to provide the particular elastin-based compositions that possess the particular functional attributes recited in

the pending claims. Accordingly, Ito et al. fails to satisfy the criteria necessary for anticipating the presently claimed invention.

To provide additional clarity as to the distinguishing features of the presently claimed invention, and to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to more particularly point out the structural and functional features of the elastin-based compositions. Applicants' amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested.

12. Claims 1 and 6-9 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Rothstein et al. Applicants traverse this rejection to the extent that it is maintained in light of the amended claims.

Rothstein et al. disclose particular polypeptides modeled on elastin and other fibrous proteins. Rothstein et al. fail to teach or suggest the particular pharmaceutical preparations provided by the presently claimed invention. Furthermore, Rothstein et al. fail to teach or suggest particular elastin based compositions that possess one or more biological activities including the ability to inhibit the proliferation of smooth muscle cells in vivo; the ability to stimulate the differentiation of smooth muscle cells in vivo; the ability to regulate the migration of smooth muscle cells in vivo; and the ability to bind to smooth muscle cells.

In accordance with MPEP 2131 and the holdings of the Federal Circuit, "a claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the claim." (*Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Accordingly, Rothstein et al. fail to satisfy the criteria established by the Courts to anticipate the claimed invention.

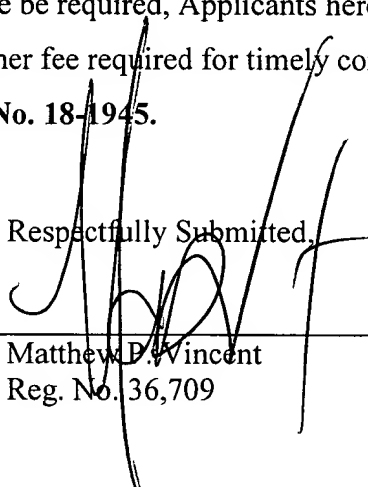
Applicants contend that Rothstein et al. fail to teach each and every element of the claims, and thus that Rothstein et al. fails to anticipate the claimed invention. Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended claim 1 to more particularly point out the claimed subject matter. Applicants

amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Respectfully Submitted,



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